DESCRIPTION

NAVIGATION OF MEDICAL INSTRUMENT

Cross Reference to a Related Application

This application is a continuation of co-pending application U.S. Serial No. 09/954,725; filed September 14, 2001.

Background of the Invention

With the German patent specification DE 198 44 767 A1, a method attaching markers to a medical instrument that are detectable under MRI is already known. The orientation of the instrument within the MRI device can be determined with these points. However, the respective allocation of the measured markers to the instrument markers is impeded due to the similarity of the signal-emitting substance to the instrument material. The non-availability of an instrument fixation to the patient proves to be a further disadvantage. Such fixation could be achieved by use of trocars. Figures 2, 3, 4, and 5 show a device ensuring a minimally-invasive approach to the brain through a hole in the top of the skull. Such trocar is already known from patent specification DE 197 26 141 and prevents the risk of the so-called Brain Shift, which signifies the uncontrolled shifting of the brain inside the surrounding skull during an operation. This problem is not limited to the neuro field, but occurs whenever shifting tissue is punctured. The disadvantages of this kind of trocars are the following points:

- The adjustment of a navigation system adapting the devices to MRI imaging to such a neuro trocar is difficult.
- The neuro trocar is manufactured of titanium alloy, so that it is depicted as a homogenous formation with indistinct rim demarcation in the MR image. A three-dimensional orientation is difficult to assess. This, however, is highly essential, with the neuro trocar, unlike a stereotactic system, having no own reference point as it is fixed to the patient.

The invention presented herein aims to solve these and other problems.

Brief Summary of the Invention

The subject invention pertains to a device for inserting medical instruments into the human body. In a specific embodiment, the subject device can be made from a material which is invisible under Magnetic Resonance Imaging (MRI). The subject device can incorporate three or more MRI compatible markers. The imaging of these three or more markers can allow the determination of the orientation of the device. A virtual image of the device can then be shown in an MRI image.

Detailed Description of the Figures

Figure 1 shows a problem of navigation.

Figure 2 shows navigation points at a device in accordance with an embodiment of the present invention.

Figure 3 shows navigation points at the instrument insertion channel of a device in accordance with an embodiment of the present invention.

Figure 4 shows angle measurement between instrument insertion channel and device in accordance with and embodiment of the present invention.

Figure 5 shows navigation with active and passive material contrast in accordance with and embodiment of the present invention.

Figure 6 shows a device with a stabilization channel in accordance with an embodiment of the present invention.

Figure 7 shows attachment of MRI markers to the combination of device, instrument and angle measuring system in accordance with an embodiment of the present invention.

Figure 8 shows linear propulsion at the instrument insertion channel in accordance with an embodiment of the present invention.

Figure 9a shows a device ensuring tilting motions of the instrument insertion channel in accordance with an embodiment of the present invention.

Figure 9b shows a sectional image of an embodiment of a device ensuring tilting motions.

Figure 10 shows a device with double-walled and contrast medium-filled top on the instrument insertion channel in accordance with an embodiment of the present invention.

Figure 11 shows adevice with motor-powered adjustable instrument insertion channel in accordance with an embodiment of the present invention.

Detailed Disclosure of the Invention

The problem of the conventional neuro trocar being not sufficiently identifiably with regard to its orientation within the MRI, as described in patent DE 197 26 141, can be solved by designing a device of a material that is totally invisible under MRI. If then a minimum of three MRI compatible points are marked on it, an exact orientation can be determined by these three points; its position in the MRI procedure can be precisely assessed, and a virtual image of the trocar can be shown in the MRI picture.

Various systems for the technical realization of these points are described below.

The problem is shown in figure 1. The medical instrument **1** with its reactive coordination system x'y'z' shall be determined in its position relative to the patient coordination system xyz.

Both the adjustment of the instrument insertion channel **10** and the adjustment of the device **3**, which essentially corresponds to the devices **1** and **2**, can be correlated to each other by an angle adjustment (see Figure 4). An angle adjustment for the azimuth angle **14** and an angle adjustment for the zenith angle **1** are possible on the device**3**. When the position of the device **3** is known, the position of the instrument insertion channel **10** will also be known automatically. By an automatic pick-off of angular movement not shown in Figure **4**, azimuth and zenith angle could be directly measured and included into the MR image. The MR image could then always adjust to the orientation of the instrument insertion channel **10** so that the operation site **16** will always be optimally in the sight vane in the imaging of the MRI device. In such case, markers according to the principles**20'**, **20''**, and **20'''** stated herein could be adapted in the device 3 or in a top for angle measurement**21**. Reversedly, it is also possible to measure

the angle within the MR image and then to adjust at the device, i.e., the device follows the MR image.

The fixation of the instrument insertion channel **10** in a certain position can be achieved by tightening a fixing screw **22** as shown in Figure 5.

Through the instrument insertion channel**10**, a tube can be inserted deep into the operation site, which will then serve as a channel for inserting further instruments as shown in Figure 6, the advantage being a stabilization of the instruments inserted under navigation. The stabilization channel **23** then holds the inserted instruments. Figures 8 and 9 show a possibility where the instrument or the stabilization channel **23** can be cramped into a mounting**6**, which is shifting in axial direction on the instrument insertion channel**10**. Such mounting **6** can be lowered manually or automatically by a motor, electrically, hydraulically, by pneumatic power or by wire pull.

The orientation of the instrument insertion channel can be achieved by tilting. To allow this, two movable laminas **7** and **8**, relative to the device **2** and shifting to each other (as shown in Figure 9), are attached to the device. The instrument insertion channel **10** is guided through an oblong opening **9** in each lamina. By mechanical manual or automatic shifting of the laminas to each other, the instrument insertion channel is tiltable in various directions. Electrical, hydraulic or pneumatic actuations are possible for automatic shifting.

A further possibility of adjustment of the instrument insertion channel**10**, as shown in Figure 11, is to position the instrument insertion channel by means such as a rotating and tilting motion via a worm wheel **11** mechanically or by motor, pneumatically, or by wire pull.

The orientation of the instrument is directly readable by the scaling at the positioning unit. It could also be monitored via the above-mentioned markers in the MR image.

In order to adapt the device to the imaging of the MRI device, a navigation system is to be integrated into the device itself. Figure 2 shows a device **2** with an instrument insertion channel **10** and three laterally extended reflectors**12**. The three mountings **13** for the reflectors **12** can be manufactured from one piece or can be three separate parts.

The reflectors **12** could also be active optical light-emitting diodes. In such arrangement, the three reflectors or sending elements **12** can be monitored by an external camera system, and, due to the relative position of these three elements to each other, the spatial orientation of the device can be calculated and then be integrated in the MR image. Better still is the application of markers which are directly identified by the "magnet" (MRI), since this will prevent inaccuracies upon matching the coordination systems.

Figure 3 shows that this navigation device can also be directly connected to the instrument insertion channel**10**. There could also be a navigation system for the device **2** a well as for the instrument insertion channel**10**, resulting in having two navigation systems working with either different wavelengths or different codification or with different geometrically designed reflectors**12**. The device can be manufactured of a material that is not depictable under MRI or with other radiological imaging methods. Single parts or areas of the device could be designed of a material that is actively or passively identifiable under MRI. For instance, the entire device for the operation under MRI could be manufactured of plastics such as PEEK, and only certain parts would be designed of titanium. The device could also be designed to have hollow spaces containing a liquid which will emit active signals, such as liquids with unpaired proton spin, for instance a gadolinium-based liquid. Figure 10 shows a double-walled top filled with a signal-emitting liquid.

Figure 5 shows a device **4** designed completely of plastics, preferably PEEK (polyetheretherketone). This device **4** is screwed into the skull with a self-cutting thread**19**. Owing to the hardness of the plastic material, the device can be manufactured with a self-cutting thread. Such plastic device **4** is preferably designed as a disposable. Two navigation points, which could be placed inside the device either separated from one another or together, shall be exemplarily described at the device. As one possibility, the adjusting screw **17**in this PEEK instrument could be made of titanium. Titanium is imaged negatively, as a black spot, in the MRI device, so that the position of the device **4** is recognizable. With two further titanium points, the orientation of the device **4** can be identified in a similar way as with the navigation system of Figures 3 or 2. A gadolinium-containing liquid is filled into a hollow space **18** in this device. This liquid is

an active liquid for the MRI device, to be imaged as a white spot in the MR image. With three such hollow spaces filled with a gadolinium-containing liquid, here also the position of the device **4** can be determined. It is now possible to combine such active spots such as the hollow spaces **18** with the respective active or passive points**17**, or self-reflecting or luminous marker points**12**, which will be identified by the MRI device or a navigation system connected to the MRI device. In this way, the localization and navigation of the device within the MRI is ensured. By use of various positioning points depicted differently in the MR image, it is possible to achieve an exact allocation of the measured points to the points at the device.

A so-called TrackPointer, as described in patent specification 298 21 944.1, can also be connected to the device by implanting it in the instrument insertion channel **10**.

The orientation of the instrument with regard to the operation system, or, in other words, the adaptation of the image to the device presented herein via the MRI device, can also be realized with the markers, according to the principle **20** stated herein, not only attached to the device **3** itself, but also to the instrument**24**, being inserted into the minimally-invasive channel **2** for a certain procedure, and to the angle measuring system **25** (Figure 7).

Figure 7 shows the process of pushing an instrument **24** through the device **3** into the operation area. A marker**20'** is placed at its distal end**20'**, a second marker**20''** in the insertion center of the device **3** as shown in Figure 5. The third marker**20'''** is positioned on the angle measuring system**25**, which is freely adjustable around the device. The plane visible in the MR image will then be extended by the three points**20'**, **20''**, and **20'''**. Thus one will always see the instrument with its inserted length in the brain region, which is determined by the third point placed on the circular angle measuring system**25**. Such marking points could also be designed as small coils, as, for example, laid open with number **200** in patent application US 5,353,795 by Sven P. Souza in Figure 2. Such an element is an active coil sending with a certain frequency and being deflected according to the system presented in the above-mentioned patent.

Such a device can be used to insert probes, for mechanical and mechanical-surgical instruments or endoscopes. The instrument insertion channel **10** could also be

designed in form of several lumens, resulting in several channels instead of only one. The device can also be used to insert larger instruments in open OP's. Such a device could be designed as either reusable or disposable instrument.

A system as presented herein can be used not only for surgical interventions and procedures, but also for the insertion of electrodes to fight Parkinson's disease. It could also be applied as a shunt.

Reference numbers

1. Device
2. Device, general for adaptation to a navigation system
3. Device
4. Plastic Device
5. Double-walled top filled with contrast medium
6. Mounting
7. Movable lamina
8. Movable lamina
9. Opening
10. Instrument insertion channel
11. Worm wheel
12. Reflector/optically emitting elements
13. Reflector fitting
14. Angle adjustment azimuth angle
15. Angle adjustment zenith angle
16. Operation site
17. Titanium screw
18. Hollow space filled with gadolinium-containing liquid
19. Self-cutting thread
20. MRI markers according to one principle presented herein
21. Top with angle adjustment
22. Fixing screw
23. Stabilization channel
24. Instrument
25. Angle measuring system